K050731

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Section 2 Summary

510(k) Summary of Safety and Effectiveness

MAY 1 9 2005

Date: March 18, 2005

Submitter: GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Lisa M. Baumhardt
Regulatory Affairs Specialist
GE Medical Systems Information Technologies
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Device: Trade Name: SEER Light Extend Compact Digital Holter System
Common/Usual Name: Digital Ambulatory Holter Recorder

Classification Names: 21 CFR 870.2800 *Electrocardiograph Ambulatory (without analysis) Medical Magnetic Tape Recorder*

Predicate Device: SEER Light Compact Digital Holter Recorder and Controller (K021470)

Device Description: The SEER Light Extend Compact Digital Holter Recorder is designed to acquire ambulatory 2 or 3 channels of ECG signal from the chest surface of pediatric or adult patients for up to 48 hours. The device stores the acquired ECG data in its on-board flash memory. The SEER Light Extend Controller downloads patient demographic information into the SEER Light Extend Compact Digital Holter Recorder and allows the user to check the signal quality of the ECG data at hookup time. At the end of the recording, the SEER Light Extend Controller is connected to the SEER Light Extend Compact Digital Holter Recorder by a cable and the stored ECG data is transferred from the recorder to the controller onto a standard compact flash memory card. Alternately, the SEER Light Connect, a USB interface, can download patient demographic information from a PC into the SEER Light Extend Compact Digital Holter Recorder and, via a PC, allows the user to check the signal quality of the ECG data at hookup time. At the end of recording, the SEER Light Extend Compact Digital Holter Recorder can be connected to the SEER Light Connect and the stored ECG data is transferred from the recorder directly to a PC.

Intended Use: The SEER Light Extend Compact Digital Holter System is intended to acquire ambulatory 2 or 3 channel ECG signals from the chest surface of pediatric and adult patients. The device stores this data along with patient demographic information to on board flash memory.

The SEER Light Extend Compact Digital Holter System is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner in a hospital or medical professional's facility.

The SEER Light Extend Compact Digital Holter System does not perform any analysis of the ECG data.

The SEER Light Extend Compact Digital Holter System is not intended for use on patients weighing less than 10Kg.

Technology: The proposed SEER Light Extend Compact Digital Holter System employs the same functional scientific technology as the predicate device SEER Light Compact Digital Holter Recorder and Controller System (K021470).

Test Summary: The SEER Light Extend Compact Digital Holter Recorder and Controller System complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the device:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration Testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental Testing

Conclusion: The results of these measurements demonstrated that the SEER Light Extend Compact Digital Holter System is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2005

General Electric Medical Systems Information Technologies
c/o Ms. Lisa Baumhardt
Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K050731
Trade Name: SEER Light Extend Compact Digital Holter System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: MWJ
Dated: March 17, 2005
Received: March 21, 2005

Dear Ms. Baumhardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050731

Device Name: **SEER Light Extend Compact Digital Holter System**

Indications For Use:
The SEER Light Extend Compact Digital Holter Recorder and Controller System is intended to acquire ambulatory 2 or 3 channel ECG signals from the chest surface of pediatric and adult patients. The device stores this data along with patient demographic information to on board flash memory.

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Prescription Use__X__ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050731